REMARKS

Currently, claims 1, 3-13, 15-19, 21, 25 -28 are pending in the application. Claims 7 and 25-28 are withdrawn from consideration. Claim 1 is amended to render it more explicit; basis is at, for example, page 9, lines 24-35 and Figure 2. New claims 35 and 36 are added, basis is in Figures 4A -4B and related text at page 10, lines 23-36.

I. APPLICANTS' INVENTION

The present invention relates to a removable device such as a stent-graft, intended for applications where it may be desirable to remove the device at some time following implantation. The stent-graft includes a helically-wound stent component provided with a covering of graft material having anisotropic strength properties. It is removable by gripping an end of the helically-wound stent component with a retrieval device and applying tension to the stent component in the direction in which it is intended to be withdrawn from the site of implantation. The use of such a retrieval device allows the stent-graft to be removed remotely, such as via a catheter inserted into the body at a different location from the implantation site. The design of the stent-graft is such that the stent component is extended axially while the adjacent portion of the graft separates between windings of the stent component. The axial extension of the stent component, with portions of the graft still joined to the stent component, allows the device to be "unraveled" (or "unwound") and removed through a catheter of diameter adequately small to be inserted into the body cavity that contained the stent-graft. It is removed atraumatically, without incurring significant trauma to the body conduit in which it had been deployed.

II. REJECTION OF CLAIMS 1, 3-6, 8-13, 15-19 and 21 UNDER 35 USC 102(b) AS ANTICIPATED BY SMITH, US PATENT 6,364,904.

The Examiner generally states that Smith discloses an endoprosthesis that includes the limitations of claim 1; limitations are then recited in sequence. The recited limitations are from the version of claim 1 as amended in an earlier paper of the Applicants (filed 3 Oct. 2007) and do not address the language of claim 1 as amended in Applicants' previous paper of 17 Nov. 2008.

The following comments are directed to claim 1 as amended herein; all remaining rejected claims depend from claim 1.

It is well appreciated that in order to anticipate a claim, the reference must teach every element of the claim.

In Smith, Applicants can find no teaching relating to removal of the disclosed stent from a patient in which it had been implanted.

Likewise, Applicants find no teaching related to splitting of the graft material between adjacent stent elements during removal.

Applicants find no teaching in Smith of applying tension to one end of the endoprosthesis to initiate splitting of an anisotropic graft material oriented so as to make this splitting due to the application of tension possible.

The Examiner is respectfully requested to point out (as called for under 37 CFR 1.104(c)(2)) the particular parts of the reference that teach or suggest these aspects of the presently claimed invention.

Smith generally teaches the construction of a stent-graft from a tape to which has been adhered a stent element (a serpentine wire; see Figures 1 and 2). This tape/wire composite is helically wound around a temporary form (such as a mandrel) to create a tubular shape. Two fundamental embodiments are taught.

The first of these two embodiments, described by Figures 3-13 and 23-34, has a substantially integral and continuous luminal surface that is referred to by Smith as a "substantially fluid tight conduit " (e.g., col. 7, lines 27-28). Smith repeatedly refers to the sealing of the overlapped tape edges that is necessary to create the fluid tight conduit; see col. 5, line 4 to col. 7, line 62 and col. 8, line 37 to col. 9, line 27. This description begins by speaking of how this embodiment "...avoids some of the *sealing and integrity* problems inherent in the prior art as the tubular intraluminal device is created." (Emphasis added.) Smith makes reference to sealing of the helical structure no less than 17 times. He is clearly stressing the importance of the integrity of the fluid tight tubular structure.

The second embodiment differs in that the adjacent edges of the helically wound tape do not overlap and are not sealed, consequently they are not continuous fluid tight tubular structures; see Figures 14-22 and related text at col. 7, line 63 to col. 8, line 36. Smith describes in this text that no seals are formed at adjacent graft strip portions of the tubular structures. These second embodiments are described (col. 8, lines 1-4) as being

"longitudinally adjustable through the use of either a self-expanding mechanism or through a pulling or pushing action by a physician, in well-known fashion." Smith repeatedly describes these second embodiments as "longitudinally adjustable' or "longitudinally expanded." It is very relevant and significant that Smith teaches that only the unsealed second embodiment without overlapping adjacent edges is longitudinally adjustable by the physician and never makes mention of any possibility of longitudinal extension of the sealed, substantially fluid tight, first embodiments. Clearly, a stent-graft that is splittable to allow removal would also be longitudinally extended during the splitting/removal process. It is quite clear that Smith never contemplated or intended such longitudinal extensibility for the fluid tight tubular structure of his first embodiment, even though he was well aware of the possibility (and value of) longitudinal extensibility for his unsealed (not fluid tight) second embodiment with gaps between adjacent edges of the tape.

Smith does not teach or suggest a fluid tight stent-graft that is intended to be removable by splitting. He makes no mention of removability from a patient. It is apparent that Smith is primarily concerned with the integrity of his fluid tight tubular structure. Indeed, he states (col. 2, lines 57-59) that "It is still a further object of the present invention to provide a tubular stent/graft that has consistent wall properties without undesired seams, bumps or weak points." (Emphasis added.) This clearly is not suggestive of a graft that is intended to be splittable. Indeed, it is quite clear that Smith is teaching a graft wherein the tubular integrity of the graft structure is paramount.

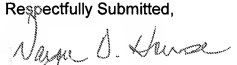
Accordingly, the present claims are not anticipated by Smith.

The Examiner stated with regard to claim 4 that it was not clear what constitutes a "small delivery profile". Applicants would point out that this phrase from claim 4 has antecedent basis in claim 1, which generally describes that the delivery profile is small with regard to the "enlarged deployed profile".

CONCLUSION

The applicants believe that their claims as amended are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance. If there remain any issues that might benefit from further discussion, the Examiner is requested to telephone the undersigned practitioner; likewise, the Applicants request an interview if such issues may remain.

Respectfully Submitted,



Wayne D. House 34,623
W. L. Gore & Associates, Inc.
551 Paper Mill Road
P.O. Box 9206
Newark, DE 19714-9206
(928) 864-2574

Date: 29 APRIL 2009